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Division of Dockets Management (HFA-305)
Food and Drug Administration (Room 106 1)
5630 Fishers Lane
Rockville, MD 20852

RE: Docket No. 2005N-0354
FDA Public Hearing on Consumer-Directed Promotion of Regulated Medical
Products
Presentations for November 1, 2005 and November 2, 2005

Dear Sir or Madam:

Pfizer Inc. requests an opportunity to provide information and evidence on the following topics at FDA's Public Hearing on Direct-to-Consumer Advertising on November 1 and 2, 2005:

- *Advancing Public Health Through **Effective**—Accessible, Understandable, and Relevant-- Consumer Health Communication*
- *Advancing Public Health Through **Clear** Consumer Health Communication*

Abstracts are attached. We request 30 minutes on "Understanding the Impact of Direct-to-Consumer Advertising on Consumers" and 20 minutes on "Principles for Clear Health Communication." Pfizer will inform FDA about the specific company representatives one week before the Hearing.

Pfizer participated actively in FDA's on-going assessment of direct-to-consumer advertising, and the agency's parallel evaluation of the constitutionality of its information management regime. We have filed extensive comments with FDA in several recent dockets, including the 2003 DTC Hearing Docket. Representatives from Pfizer also testified at that Hearing. As the largest pharmaceutical company in the world, and as a leading voice on the importance to the public health of the ongoing provision of actionable health information, Pfizer urges FDA to grant its request to participate.

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Pfizer is committed to studying how best to provide information about our prescription medicines in order to meet the public's and the medical community's needs.

We look forward to the opportunity once again to contribute to FDA's efforts to learn how DTC health information can remain a relevant public health driver.

Respectively submitted,

PFIZER INC.

By: Arnold I. Friede
Arnold I. Friede

PFIZER DTC HEARING ABSTRACT

Advancing Public Health Through Effective—Accessible, Understandable, and Relevant— Consumer Health Communication

Too many Americans who need medical help still don't receive it. This leads to unnecessary suffering and high-cost, acute-care medical interventions. Accessible and motivating (i.e. understandable and relevant) health information is essential for the public to become more engaged in their health care and to manage health care decisions as active partners with healthcare providers. At the Hearing, Pfizer will review the strong empirical record proving the public health value of direct-to-consumer (DTC) advertising of prescription medicines. We will discuss techniques, challenges, and opportunities in crafting appropriate DTC communications.

Benefit and Risk Information in DTC Communications

Research shows that DTC advertising encourages people to seek out additional health information. This reinforces the proposition that DTC communications should be designed as a catalyst for the public to seek out more in-depth information, including active dialogue with their health care providers about the benefits and the risks of a prescription medicine. It argues for the notion that DTC ads – especially television ads – should be viewed as a vehicle for providing the most important information about benefits and risks. An individual DTC advertisement should not be viewed as a single comprehensive source of all possible benefit and risk information. There are other complementary vehicles that allow for more detail. Our experience shows that patients must overcome significant barriers in order to seek out medical help and to engage in healthy behaviors, such as appropriate evaluation and treatment of medical conditions. It is critical, then, to strike the right balance in the communication of benefit and risk information in DTC ads so that we neither underwarn nor overdeter the public. FDA must be mindful that, in its current form, DTC advertising has been effective in providing relevant information that: 1) raises awareness of medical conditions and treatment options; 2) encourages the public to talk to their healthcare providers; and 3) helps millions of people get diagnosed early, and appropriately treated for medical conditions.

Improving DTC Communication to Meet the Public's Health Information Needs Better

The pharmaceutical industry is improving DTC advertising in several areas, including benefit and risk communication, to better meet the public's needs. The recent adoption of the PhRMA Guiding Principles for DTC Advertising will help the public benefit further from accurate and timely information that encourages discussion of medical conditions and treatment options with healthcare providers.

In addition, Pfizer itself recently announced a series of changes to its DTC advertising practices that aim to improve the communication of benefit and risk information, encourage a better patient-physician dialogue, and motivate people to overcome the substantial barriers to better health. These changes are based on research and ongoing dialogue with consumers, healthcare providers, and other key stakeholders. We believe that, as a result, millions of Americans will benefit even more from accessible and motivating health information that encourages them to visit their doctor and uncover health conditions earlier and then appropriately address them.

More Empiric Evidence Is Needed To Understand Better How Consumers Process Health Information

As new questions continue to be raised about information in DTC advertising, Pfizer intends to pursue additional empirical research to fill in the data gaps and thereby help inform empirically-based policy in this area. At the Hearing, we will address the need for research that is focused on better understanding how consumers process information in DTC advertising and how this implicates the presentation of benefit and risk information. In addition, we will outline key questions that aim to help define and measure how important health information can be more effectively imparted and received through mass communications.

Earlier this year, Pfizer committed to conduct research about the public's understanding of benefit and risk information in DTC television advertising, similar to the comprehensive research we conducted on the brief summary in DTC print ads. This research can help guide establishment of reasonable and achievable goals and guidance for benefit and risk communication in DTC advertising. We solicit participation in this research from FDA and other interested stakeholders.

PFIZER DTC HEARING ABSTRACT

Advancing Public Health Through Clear Consumer Health Communication

In today's health care environment, people are more responsible for and involved in health care decisions. Studies establish that people need and want clear and understandable health information that raises awareness of medical conditions and appropriate treatment options.

At the Hearing, Pfizer will present research-based best practices for developing clear and understandable health information. These practices are grounded on more than eight years of primary and secondary research, literature reviews, and expert consultation that Pfizer has conducted on health literacy and its impact on the public's understanding of health information.

Benefits of Making Prescription Medicine Information Health Literate

In order to help the public be an active participant in health care decision-making, health information needs to be clear and understandable. However, health information tends to be complex and is generally not designed to suit audiences without medical understanding, e.g., package inserts in prescription medicines, and traditional brief summary information that usually accompanies prescription medicine print advertisements. As a result, consumers often have difficulty reading and understanding health information. Studies have shown that when health information is presented in a clear, understandable, and easy-to-read format, millions more consumers actively engage in their healthcare. We encourage FDA to be cognizant of Clear Health Communications Principles in developing DTC communications policies and regulations.

Employing Clear Health Communication Principles

Through research conducted with consumers, healthcare providers, and health literacy experts, Pfizer has found that patients are more engaged when health information: 1) uses clear and concise language; 2) sequences information in an order that highlights the most important information that consumers want and need; 3) uses "patient-friendly" formats, and 4) contains understandable risk information. Employing these practices improves understanding of benefits and risks of prescription medicines and also helps to encourage the public to actively engage in their health care. This leads to better health outcomes.

Pfizer has used its research findings to create Clear Health Communication Principles that inform all of our print consumer communications, including all of our print DTC advertisements. We also have adopted research-based best practices to apply to our product Web sites by the end of 2006. Through application of these principles, Pfizer's consumer communications will help to engage millions more people in their healthcare.

Pfizer has also conducted research, in partnership with the National Consumers League, COSHAR Foundation, National Council on Aging, and with practicing physicians, to improve consumer understanding of the information contained in the print brief summary that is used with all print DTC ads. The findings of this research resulted in Pfizer's commitment to utilize a new

consumer-friendly and consumer-tested “Important Facts” print brief summary. Pfizer is working with the FDA to implement the “Important Facts” improvements in its DTC print advertising.